Measures by MHLW toward 5-Year Clinical Trials Vitalization Plan 2012
- Measures taken in 2012 and Outline of 2013 Plan -

May 13, 2013
Research and Development Division, Health Policy Bureau, MHLW
Previous Clinical Trials Vitalizeation Plans and Transition of No. of Drug Clinical Trial Notification (CTN)

Enactment of new GCP

3-year nation-wide clinical trials vitalization plan (extended by 1 year)

New 5-year clinical trials vitalization plan

5-year clinical trials vitalization plan 2012
All-Government Strategy and Measures toward Future Clinical Trials Vitalization

Comprehensive Strategy for the Rebirth of Japan
(July 2012 Cabinet Decision)

[Life Science Growth Strategy] [Intermediate Goal for 2015]
- 800 applications for clinical trials (including 150 from global clinical trials and 20 trials led by investigators)
- Approval of 30 units of new medical devices

5-Year Strategy for Health Care Innovation
(decided on by the Health Care Innovation Council on June 6, 2012)

5-Year Clinical Trials Vitalization Plan 2012
(March 30, 2012 MEXT/MHLW)
1. Further leap and independence of clinical trial sites based on the past 9 years’ activation plan

2. Measures toward the creation of innovative drugs, medical devices etc. originating in Japan (Innovation)
1. Further Leap and Independence of Clinical Trial Sites Based on 9 years’ Activation Plans

(1) Speed up enrolment of trial subjects (mainly trials led by companies)

- Promotion of clinical trial networks by utilizing joint IRB, strengthening function of network secretariat office

(2) Streamline administrative procedures for clinical trials (mainly trials led by companies)

- Full enforcement of measures in “Report on More Efficient Clinical Trials”
- Full utilization of uniform forms

(3) Develop and secure human resources such as investigators (common to clinical trials and researches)

- Continuous training for CRCs and IRB members
- Foster investigators and health care professionals familiar with clinical trials

(4) Raise people’s/patients’ awareness of clinical trials (common to clinical trials and researches)

- Raise awareness of significance of clinical trials

(5) Rationalize cost (mainly trials led by companies)

- Thorough enforcement of fee-for-service system and investigation of rationalizing clinical trial costs

(6) Make better use of IT etc. (common to clinical trials and researches)

- Application of IT to IRB procedures, etc.
(1) Speed up Enrollment of Trial Subjects  
(mainly trials led by companies)

[Goal]  
At least 3 excellent clinical trial networks in Japan.

<Short-term Objectives>
- Thorough enforcement of measures in ”Report on More Efficient Clinical Trials”
- Promotion of clinical trial networks

<Mid and Long-term objectives>
- Establish disease-specific clinical trial networks
- Reconsider type of contract in clinical trial networks
Set a goal to establish clinical trial networks allowing for enrolment of trial subjects equivalent to those in mega hospitals in Asian countries.

One mega hospital (2000 beds) in Asian countries VS 3-5 hospitals in Japan (500-bed hospital × 3)

At least 3 - 5 hospitals are needed that can always actively cope with any disease areas through collaborating and functioning “as if they were single hospital”.

One Stop Service

- Prepare SOP and Unify various forms
- Establish and make use of joint IRB
- Active management of secretariat office of clinical trial networks
Revision of GCP Ministerial Ordinance, etc. (December 28, 2012)
Allowing for One Stop Service for Clinical Trials led by Companies, Investigators

**Purpose of Revision**
- Streamline clinical trial procedures and speed up clinical trial business, while assuring international harmonization.
- Reduce burden of clinical trials led by investigators and promote collaboration between industry and academia in unmet-needs areas.

**Outline of Revision**
- Network joint secretariat offices centering on clinical trials core hospital can do unified contract of clinical trials.
- In clinical trials led by investigators, “Representative coordinating investigators who submit CTN” can be “investigators who conduct the clinical trials”, in order to make CTN and AE reporting procedures more efficient, which are submitted under joint names of investigators.
- In clinical trial contracts, target number of subjects in each hospital is not required (which ensures efficient enrolment of subjects).
- Clarification is made that collation with raw data is not necessarily needed for all clinical trial data, which allows for more efficient monitoring by sampling of SDV, central monitoring, etc. in clinical trials core hospitals.
- Promote application of IT to clinical trial documents so as to speed up communication and reduce burden at clinical sites.

**Previous clinical trial system**
- Sponsor contracts with each hospital → huge burden
- Sponsor needs to individually make contracts with hospitals, which bears a great burden.
- Forecasting enrolment of subjects is difficult, which results in many contract alterations, complicated procedures, and increased costs.

**Cooperation with clinical trials core hospitals**
- Unified counter function enables subject enrolment more efficient, leading to cost reduction.
- Multicenter trials led by investigators can be conducted efficiently.
Image of clinical trial networks

Request of procedure, transmission of information, etc.

Network Secretariat Office

Transmission of information

Sponsor

Joint IRB, etc.

Integration of information

Simultaneous submission of documents, integration of information

Relevant Medical Institutions
Example of disease-specific network
Network of Pediatric Clinical Trials
Grant-in-Aid Program for Collaboration Platform in Priority Areas of Clinical Trials
(2010 - 2012)

In clinical trials that need collaboration of multiple hospitals for specific diseases and specific patient populations, “Collaboration Platform for Priority Areas of Clinical Trials” will be established through the following steps:

- Unified functions of contact with encounter for sponsors
- Central Institutional Review Board (IRB) Function
- Progress management of ongoing clinical trials

Program outline

<table>
<thead>
<tr>
<th>Previous clinical trial system</th>
<th>Collaboration centering on National Center for Child Health and Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor makes contract with each hospital</td>
<td>• unified counter function • central IRB function</td>
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<tr>
<td>• huge burden</td>
<td>Platform in priority areas of clinical trials</td>
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</table>

- Sponsors need to individually make contracts with hospitals, which bears a great burden.
- Forecasting enrolment of subjects is difficult, because progress management of clinical trials is not unified.

Budget in 2012: 0.16 billion yen

→ Help promote clinical trials in specific areas that can hardly be forwarded based on incomes only from the trials, leading to support their independence.
(2) Streamline Administrative Procedures for Clinical Trials (mainly trials led by companies)

[Goal]
- Uniform forms are used without alteration by all hospitals participating in The Council for Clinical Trials Vitalization.
- Number of clinical trial networks with joint IRB is increased.

<Short-term objectives>
- Full enforcement of measures in “Report on More Efficient Clinical Trials”
- Strengthen secretariat function of clinical trial networks
- Full enforcement of applying uniform forms (“Uniform forms for clinical trial request”[Notice])
  (HPB RD No. 0307-1 and PAFSC No. 0307-2 dated March 7, 2012
   Notice by Manager, Research and Development Div., Health Policy Bureau, and Manager, Evaluation and Licensing Div., Pharmaceutical and Food Safety Bureau, MHLW)
- Application of IT
- Utilization of joint IRB, etc.
- Improvement of management of clinical trials led by investigators
(3) Develop and Secure Human Resources such as Investigators (common to clinical trials and researches)

[Goal]

- Foster at least 500 senior clinical research coordinators.
- Ratio of permanent employees is increased among human resources such as CRC who engage in clinical researches/trials in medical institutions that perform relevant researches/trials.

<Short-term objectives>

- Education and training about clinical researches/trials (Junior and Senior CRC, Local Data Manager, IRB member, etc.)

<Mid-and Long-term objectives>

- Foster investigators familiar with clinical research/trial.
- Foster medical professions familiar with clinical research/trial.
- Secure human resources that can engage in clinical research/trial.
(4) Raise people’s/patients’ awareness
(common to clinical trials and researches)

[Goal]
- Contents of MHLW clinical trial website are enriched and receive increased number of hits.
- Portal site of clinical research (trial) receive increased number of hits.

<Short-term objectives>
- Raise awareness on significance of clinical research/trial
  - Exchange opinions between pharmaceutical industries, medical academia, and patient groups
  - Enrich and make better use of the website
  - Public relation in the occasions of ”Week of Medicine and Health”, etc.
  - Education of and information for children
- Provide information about on-going clinical researches/trials
  - Improve “Portal site to search for clinical researches/trials”
  - Provide information about IRB/ERC

<Mid-and Long-term objectives>
- Release information about on-going clinical trials and status of GCP observance, etc.
(5) Rationalize Cost  (mainly for clinical trials led by companies)

[Goal]
- Model plan of point table is formulated which corresponds to global clinical trial, etc.
- Fee-for-service system is adopted by medical institutions that participate in The Council for Clinical Trials Vitalization.

<Short-term objectives>
- Adoption of fee-for-service system
- Further awareness on scope of combining insurance and non-insurance coverage in clinical trials

<Mid-and Long-term objectives>
- Study on appropriating clinical trial costs in Japan
- Study on expanding scope of combining insurance and non-insurance coverage for medicines with indications equivalent to investigational drugs in investigator-initiated “Chiken” trials
(6) Make better use of IT etc. (common to clinical research and trial)

[Goal]
- There are more medical institutions that have equipment for EDC and more clinical trials that use EDC.

<Short-term objectives>
- Application of IT to IRB procedures, etc.
- Promotion of better use of EDC
- Research and Development toward SDV introduction

<Mid-and Long-term objectives>
- Measures toward linkage of hospital IT system and EDC
- Investigation toward introduction of SS-MIX standardized storage and CDISC standard
- Investigation on use of cloud computing, etc.
- Investigation on appropriate state of mega data base of medical information based on certain rules
2. Measures toward the creation of innovative drugs, medical devices etc. originating in Japan (Innovation)

(1) Improve infrastructure for clinical researches/trials.
- Create centers to conduct high-quality clinical research/trial (centers to support translational research, centers for early/exploratory clinical study, and clinical trials core hospitals, etc.)
- Foster and deploy clinicians having clinical research planning ability

(2) Improve ethics and quality in clinical researches.
- Study toward ethical policy stipulating quality of clinical research in addition to protection of participants
- Improve quality of review through enriching education to committee members and introducing IEC recognition system, etc.
- Study toward registration of clinical research

(3) Strengthen measures in areas where development is hardly advanced
- Measures toward pediatric diseases, rare and refractory diseases, medical devices/advanced medicine, etc.
- Prioritizing allocation of research budget, etc., to clinical research of high quality

(4) Cope swiftly with large-scale natural disasters
Late-Stage Clinical Trials closer to clinical practices

Large-scale clinical research leading to development of standard therapy

Strengthen Environment for Clinical Trials Other Than “Late-Stage Development”

Report from Study Group on Mid-Term Evaluation of New 5-Year Clinical Trials Vitalization Plan

(Report dated January 19, 2010)
Despite of seeds originating in Japan, clinical trials/researches in U.S. and Europe go before Japan, which sometimes benefit Japanese patients only after those in U.S. and Europe.
Centers for early/exploratory clinical studies were created at 5 sites from FY2011 to conduct clinical researches for initial treatment in human with new drugs/devices for the first time in the world. Furthermore, clinical trials core hospitals that play the central role in the conduct of internationally standard (ICH-GCP compliant) investigator-initiated clinical trials with the aim of improving the quality of clinical trial data in Japan were created at 5 sites from FY2012, and other 5 sites will be created from FY2013.

* Comprehensive Strategy for the Rebirth of Japan clearly describes that clinical trials core hospitals will be created in 15 sites during 3 years from FY2011.

For 5 existing medical institutions as centers of early/exploratory clinical studies with infrastructure allowing for initial clinical trials in human, systems are reinforced focusing on [cancers] [neuropsychiatric disorders] [cerebral and cardiovascular disorders], etc.

For 5 existing medical institutions as clinical trials core hospitals that initiated infrastructural arrangements for overall clinical researches, systems will be reinforced in FY 2013 focusing on [cancers] [regenerative medicine], etc. For 5 other medical institutions that will initiate infrastructural arrangements from FY 2013 on, systems will be reinforced focusing on investigator-initiated clinical studies in [intractable/rare/pediatric diseases, etc.] area with a small number of patients where companies are reluctant to lead clinical trials, as well as focusing on network establishment.

Creation of Clinical Trials Core Hospitals

Budget Plan FY2013= 3.1 billion yen

- Clinical researches in human: led by investigators
  - Clinical trials: led mainly by companies

Early/exploratory clinical research centers (5 established sites)

- Clinical trials core hospitals (5 established and 5 upcoming sites)
  - actively conduct clinical trials for pediatric, intractable diseases, etc.
  - conduct clinical research of high quality, leading to swift application for approval

Clinical research (development stage)

Investigator-led Clinical trial

Company-led Clinical trial

Basic researches in Universities, Institutions

Basic research in companies

Clinical research (post-marketing)

fruits

creation of evidence for optimal treatment

- centers for early/exploratory clinical research
  - Budget for arrangements: plan in FY2013 0.94 billion yen (0.94 billion for reinforcement)

Clinical trials core hospitals
  - Budget for arrangements: plan in FY 2013 2.16 billion yen (1.3 billion for reinforcement, 0.86 billion for new establishments)
Major Requirements for Center of Early/Exploratory Clinical Research

All 3 conditions below must be met

1. Advanced treatment hospitals, national centers for advanced and specialized medical care, or hospitals equivalent to them.
2. Having doctors familiar with clinical trial/research in focused area such as cancer, cerebral and cardiovascular diseases.
3. Having systems to promptly cope with serious adverse events, including night and holidays.

Having concrete plans to complete following support system

**Staff Deployment**
- Staff deployment which enables investigators familiar with clinical trial/research to concentrate on the clinical trial/research
- Deployment of senior clinical research coordinator (CRC) who engages in planning of clinical trial, and deployment of CRC who can fully cope with early/exploratory clinical trials
- Staff to explore seeds in universities, institutes, and venture companies
- Staff with experience in regulatory organization that approves drugs
- Staff familiar with intellectual property and technical transfer
- Biostatistician, Data Manager (DM), Project Manager
- Staff to coordinate with collaborative hospitals when obtaining POC, etc.

**System**
- Proper safety management system to cope with emergency cases
- Independent data management system
- Proper monitoring system and audit system to assure reliability
- System that assures proper review from standpoint of morality, science, safety, reliability, proper management of transparent IRB, and proper control of COI (conflict of interest)
- Joint research system with collaborative hospitals when obtaining POC
- System allowing for education to interested parties as well as promotion/enlightenment/public relation to citizens, etc.
Early/Exploratory Clinical Trial Centers

- National Cancer Center  
  (Drug/Cancer Field)
- Osaka University Hospital  
  (Drug/Cerebral-Cardio-Vascular Field)
- National Cerebral and Cardiovascular Center  
  (Medical Device/ Cerebral-Cardio-Vascular Field)
- The University of Tokyo Hospital  
  (Drug/Psychiatry and Neurology Field)
- Keio University Hospital  
  (Drug/Intractable Immune Disease Field)

(Adopted in July 2011)
7 Function required to Clinical Trials Core Hospitals

[Responsibilities of Hospital Director]
I. Arrangement for department administrators, et al. in establishing functions all around the institution necessary to the clinical trial core hospital

[Planning and Enforcement]
II. Ability of proper planning with consideration of exit strategy, and to conduct ICH-GCP * compliant clinical research
   * Medical devices should be ICH-GCP or ISO14155: 2010 compliant. The same shall apply hereinafter.

[Ethical Review]
III. Ability of proper and highly transparent ethical review from standpoint of morality, science, safety and reliability

[Data Reliability Assurance]
IV. Ability of ICH-GCP compliant data reliability assurance

[Intellectual Property Management]
V. Ability of seeds-related intellectual property management and technical transfer

[ARO Function]
VI. Ability of high-quality clinical research planning/performance with other hospitals. Ability as core hospital to support clinical research in other medical institutions.

[Education and Public Awareness]
VII. Ability of education to concerned parties, promotion, public awareness, and public relation to citizen and patients.
Clinical Trials Core Hospitals
(institutions selected in FY2012)

- Hokkaido University Hospital
- Chiba University Hospital
- Nagoya University Hospital
- Kyoto University Hospital
- Kyushu University Hospital

(Adopted in May, 2012)
Clinical Trials Core Hospitals
(institutions selected in FY2013)

- Tohoku University Hospital
- Gunma University Hospital
- National Center for Child Health and Development
- National Hospital Organization Nagoya Medical Center
- Okayama University Hospital

(Adopted in April, 2013)
1. **Promote development of drugs and medical devices**

Create the newest healthcare environment to which people can access without anxiety, develop innovative drugs and medical devices originating in Japan using Japanese *monozukuri* (skill to make products) power, aim to “generate fortune through growth”, realize activation of healthcare-related market and economic growth of Japan, and actively advance to overseas markets.

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**[1] Strengthen support of drug development**

- Create All-Japan support system for drug development in collaboration with related ministries and independent administrative research institutions.
- Strengthen biomedical-related support equipment, etc.

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**[2] Create environment for clinical researches and trials**

Create clinical trials core hospitals

- Conduct high-quality clinical researches and Investigator-led clinical trials including intractable and pediatric diseases.
- Center for highly advanced medical technology
- Function as a center of large-scale network of multiple hospitals, etc.

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**[3] Enrich and strengthen measures for review and safety**

- Expand consultation of regulatory strategy in PMDA
- Strengthen safety measures and provide technological feedback, etc.

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**[4] Strengthen drug R&D in focused areas and regenerative medicine**

- Strengthen researches toward application of innovative drugs, medical devices, etc. mainly in 8 focused areas including cancer, intractable/rare diseases.
- Promote drug discovery research in regenerative medicine area

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**[5] Support domestic pharmaceutical industry’s advance into overseas by funding from public and private sectors**

- Support research and development of drugs for developing countries by public and private sectors.
Current Global Clinical Research → focusing on diseases that meet needs in Europe and U.S.A.

Protocol of Global Clinical Trial

Led by Mega firm → EU · U.S.A → Led by Academia

plays mainly reception role in global clinical researches led by other countries (EU, U.S.A)

Future Global Clinical Research → Toward evidence building for Japan- and Asia-specific diseases

Asian countries

Japanese leadership in global clinical research
- From a member to the leader -

Plan & design of strategic protocol

Presentation of articles from clinical research outcomes to be published in world prestigious medical journals → Evidence for guideline of clinical practice

*gastric cancer, lung cancer, ATL, medical devices suitable to Asian physiques, etc.
(1) Improve Infrastructure for Clinical Trial/Research

[Goal]
- Establish 15 or so clinical trials core hospitals (including early/exploratory clinical trials) and 2 centers for global clinical researches led by Japan.
- Each center supporting translational research will initiate investigator-led clinical trial with at least 3 seeds.

1. Clarify the positioning of each center and promote high-quality clinical research.
   <Short-term objectives>
   Centers to Support Translational Research*
   Centers for Early/Exploratory Clinical Research
   Clinical Trials Core Hospitals*
   Centers for Global Clinical Research Led by Japan* etc.
   (*System to support performance of clinical research [e.g. ARO, etc.])

2. Foster key human resources
   - Foster and deploy clinicians having clinical research planning ability
(2) Improve Ethics and Quality of Clinical Research

[Goal]
- Revise “Ethical Guidelines for Clinical Studies” by FY2013.
- Joint Ethical Review Committee (ERC) will be set up by clinical trials core hospitals and it will conduct contract review of external institutes’ clinical researches.
- Establish system to recognize ERC.

[1] Consider revision of “Ethical Guidelines for Clinical Studies” (by 2013)

[2] Promote high-quality clinical research and investigate appropriate state for protection of participants in clinical research

<Short-term objectives>
- Improve quality of ERC, etc.
  (Enhance education to committee members, provide information of member list, procedures, proceedings on web, promote joint ERC, etc.)
- Consulting office for participants in clinical research

<Mid- and Long-term objectives>
- System to authorize ERC
- Compensation to participants

[3] Measures for ERC to cope with advanced clinical trials, etc.
Consider revision of “Ethical Guidelines for Clinical Studies” (by 2013)
- Consider stipulating quality of clinical research in addition to protection of participants
- Consider registration of clinical research

### (2) Improve Ethics and Quality of Clinical Research

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<tr>
<th>1st</th>
<th>December 27, 2012</th>
<th>Joint meeting of Expert Committee on Revision of Ethical Guidelines for Epidemiological Research and Expert Committee on Revision of Ethical Guidelines for Clinical Research</th>
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<td>2nd</td>
<td>February 20, 2013</td>
<td>1st Joint Meeting on Revision of Ethical Guidelines for Epidemiological Research and Ethical Guidelines for Clinical Research</td>
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<td>Ministry of Education, Culture, Sports, Science and Technology</td>
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<td>Round-Table Conference on Revision of Guidelines for Epidemiological Research (tentative name)</td>
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<td>Technology Subcommittee, Council for Health Science</td>
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</table>
(3) Strengthen measures in areas where development is hardly advanced

[Goal]
· Increased number of investigator-led clinical trials for pediatric diseases, rare/intractable diseases, etc.

[1] Measures toward pediatric diseases, rare/intractable diseases
   <Short-term objectives>
   · Incentive for development in those areas
     (Foster research groups, enrich support by using Health Labour Sciences Research Grant, etc.)

   <Mid-and Long-term objectives>
   · Provide information about clinical trials for rare/intractable diseases

[2] Measures toward medical device/advanced medicine
[3] Financial support, etc.
[4] Regulatory system
(3) Strengthen measures in areas where development is hardly advanced

**Goal**
- Increased number of investigator-led clinical trials for pediatric diseases, rare/intractable diseases, etc.


  **<Short-term objectives>**
  - System to conduct clinical research/trial for medical device
  - Efficacy assessment, etc. in the course of medical device development
  - Train human resources to engage in medical devices
  - Measures toward advanced medicine

  **<Mid-and Long-term objectives>**
  - Issues when performing clinical research/trial of medical devices

[3] Financial support, etc.

[4] Regulatory system, etc.
(3) Strengthen measures in areas where development is hardly advanced

[Goal]
- Increased number of investigator-led clinical trials for pediatric diseases, rare/intractable diseases, etc.

[1] Measures toward pediatric diseases, rare/intractable diseases

[3] Financial support, etc.

<Short-term objectives>
- Allocation of research grant to clinical researches
  (Prioritized allocation of the grant to high-quality researches, etc.)

<Mid-and Long-term objectives>
- Enrich financial aid to investigator-led clinical research/trial from private sector
- Appropriate state in unifying organizations that allocate grant to clinical researches

[4] Regulatory system, etc.

<Mid-and Long-term objectives>
- Handling of health insurance for clinical research by using approved drugs/medical devices
(4) Cope swiftly with large-scale natural disaster

[Goal]
- By FY2014, model manual is prepared to secure safety of participants in clinical trial/research and ensure reliability of data in the event of disaster.
- Medical institution and sponsor establish the system to cope with large-scale disaster by preparing contingency planning manual based on the model manual.

[1] Security of subjects, etc.
- Study appropriate state of manual for clinical research/trial in the event of disaster
- Prepare contingency planning model manual etc.

[2] Secure data reliability, etc.
- Medical institutions study measures to secure data reliability in the event of disaster.
Seamless Support System
-From Basic Research to Clinical Research/Trial (Drug)-

Basic Research

Non-clinical Study

Clinical Trial
  Early-Stage
  Late-Stage

Review/Approval

Translational Research Support Centers (MEXT)

Early/Exploratory Clinical Trial Centers

- Centers for Global Clinical Research Led by Japan
- Network for Pediatric Clinical Trial

Clinical Trials Core Hospitals
[Researches from FY2012]

**Designated Research <Create Manual against Disaster>**
- Research on Creating Manual for Clinical Trial to Cope with Large-Scale Disaster (FY2012-2013)
  Chief Researcher: Dr. Kazunori TAKEDA (National Hospital Organization Sendai Medical Center)

**Designated Research <Examine toward Revision of Ethical Guidelines for Clinical Research>**
- Comparison between Domestic Guidelines and Systems in Foreign Countries (FY2012)
  Chief Researcher: Dr. Yasuhiro FUJIWARA (National Cancer Center)

**Public Recruitment <People’s Public Awareness about Clinical Research/Trial>**
- Research on People’s and Patients’ Awareness about Clinical Research/Trial (FY2012-2013)
  Chief Researcher: Dr. Hajime SATO (National Institute of Public Health)
- Research on Content Creation of Clinical Trial and Establishment of Portal Site Based on General User’s Viewpoint (FY2012-2013)
  Chief Researcher: Dr. Etsuko ARITA (Kitasato University School of Pharmacy)

**Public recruitment <Human Resource Development of Investigator and Clinical Trial Support Staff (e-learning)>**
  Chief Researcher: Seiichiro YAMAMOTO (National Cancer Center Hospital)
- Research on Development of E-learning system for Clinical Research/Trial Corresponding to Occupational Categories and Levels through Coordination of Universities (FY2012-2014): Chief Researcher: Dr. Daisuke KOIDE (The University of Tokyo)

**<Evaluation and Licensing Div.>**
- Research on Operation of Investigator-Oriented Clinical Trials (FY2012)
  Chief Researcher: Dr. Hiroshi WATANABE (Hamamatsu University School of Medicine)
<Promotion of Clinical Trial Networks>

<Education and Training on Clinical Research/Trial>
As to Junior CRC and senior CRC, clarify what human resources are required. Study, prepare and conduct standard curriculum of training for junior staff.

<Study toward Establishment of Disease Registry>
Study definition of disease registry, characteristics of network, and appropriate state of disease registry to comply with its purpose, etc.

<Appropriating Cost of Clinical Trial>
Study calculation method of contract costs for clinical trial. Propose appropriate model, etc.

<Study Application IT to Clinical Trial>
5-Year Clinical Trials Vitalization Plan
Goal in 2012

1. Provide **Japanese citizens** with medically needed drugs and devices **swiftly**.
2. Develop innovation out of the seeds **originating in Japan** into **practical use**.
3. Build up evidence to seek for **optimal treatment** based on combination of post marketing drugs.

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**Raise medical standard level of Japan**

**Express innovation originating in Japan into the world**
Thank you for your attention.

Let’s advance clinical research/trial by efforts of all concerned!!

Office of Clinical Trial Promotion
Research and Development Division,
Health Policy Bureau, MHLW